CLIAC RECOMMENDATIONS
for
Good Laboratory Practices for Waived Testing
February 16, 2005

Considerations Before Testing

- Considerations before testing are the most critical issues, and persons providing/using the test will benefit from considering all these issues. When deciding whether to perform waived testing or considering the addition of a specific waived test to the testing menu, management or the laboratory director should weigh the following:
    - Careful consideration and evaluation of a test prior to use is a critical issue and is part of assuring patient safety
    - Each test should be evaluated for use in the individual practice or test site
    - The person assessing the test should have appropriate background/training
    - The laboratory director is accountable for the laboratory results; the director/physician should approve/sign-off on all new tests
    - Maintenance of records, including records of testing results (includes where records will be stored and who will have access to records)

Determine Whether State Regulations Apply

- State and local requirements may be more stringent than CLIA (Clinical Laboratory Improvement Amendments of 1988) requirements for performing laboratory tests
    - The guidelines should include information on where to find state laws/regulations

CLIA Certificate of Waiver (CW)

- A CLIA Certificate of Waiver (CW) or other CLIA certificate must be obtained prior to performing any laboratory testing
- To obtain the CW
    - Complete Centers for Medicare & Medicaid (CMS) Form 116 (CMS website: http://www.cms.hhs.gov/clia/cliaapp.asp)
    - Submit the fee
- The CW must be renewed every two years
- CW laboratory requirements
    - Testing is limited to tests/test systems categorized as waived
    - Follow manufacturer's instructions for testing
        - Any modification of the test procedure or use of the test changes its complexity to uncategorized (high complexity) and it cannot be used by a facility with a CW
    - CW facilities are exempt from CLIA standards
        - No routine oversight/inspections by CMS
        - CLIA personnel standards do not apply
- Identify a person responsible for oversight and document the delegation
- The "point person" or person who is accountable should sign the CW application

- The Food and Drug Administration (FDA) should require manufacturers to include instructions for obtaining a CW in test system information

- Clarify the term "testing site," to include non-traditional testing sites (e.g., nursing homes, mobile laboratories, field sites) covered by a CW
- Stress that testing personnel should know the location where the CW is maintained
- Provide specific examples of the responsibilities of the director or responsible person, such as signing the CW application, receiving product notifications and recalls, and taking appropriate action
- Avoid use of the acronym "COW" in publications; it may give a negative impression

Management Responsibility for Safety

- Provide safe environment for personnel and patients
    - Distinguish between CLIA, OSHA (Occupational Safety and Health Administration), and HIPAA (Health Insurance Portability and Accountability Act of 1996) requirements
        - Regardless of the type of CLIA certificate, a facility must comply with OSHA requirements, which are independent of CLIA
        - Staff handling human specimens should have information on bloodborne pathogens and contamination
    - Explain adequate space, using examples
- Comply with OSHA, state, and local requirements for handling and transport of human specimens, disposal of biohazard waste, availability of hepatitis B vaccine
    - Provide state websites to access information, or a state contact. State Survey Agency contact information can be found on CMS website http://www.cms.hhs.gov/clia/ssa-map.asp
    - Provide resources for additional information
- Have a separate specimen collection area
    - Eating and drinking are not permitted where specimens are collected or testing is performed
    - Post good laboratory practice information for patients
- Designate and maintain a "clean area" and the appropriate physical environment for testing
- Emphasize the importance of following Universal Precautions
- Provide resource information (e.g., FDA, CMS, MedWatch)

Diagnostic and Patient Benefits

- Diagnostic and patient benefits should be met by the test
    - Emphasize decision-makers should understand and abide by the intended use as described in the product insert
        - Product information should indicate if the test is a screening or diagnostic test
        - Medical indications/limitations affecting the test
            - Limitations of the test must be understood
        - Appropriate patient population for test performance
        - Test performance (accuracy, predictive values) in varying prevalence populations
    - Review accuracy and precision information provided in the product insert
    - Patient follow-up, counseling, confirmatory testing needed

        - Limitations of the test should be clarified and communicated to the patient
    - Balance patient benefits of waived testing, including immediate accessibility for patient care and treatment, with cost considerations

Physical Requirements for Testing

- Consider the physical requirements for conducting testing
    - Laboratory environment – temperature, humidity, adequate lighting, electrical requirements
        - Explain that, for many test systems, manufacturers' instructions indicate the acceptable environmental temperature range for testing and/or test system/reagent storage
    - Workflow, space required for testing, equipment, storage of tests/reagents/supplies
    - Additional equipment and disposal needs
    - Ensure staff access to sinks for hand washing or antiseptic gels for "dry" cleaning

Total Cost Considerations

- Factors to be considered in assessing the total cost of testing
    - Inventory control
    - Shelf life (expiration dates) of test components and supplies
    - Items not supplied with test
    - Cost of performing control procedures/maintaining equipment
    - Total volume of testing/seasonal testing
    - Personnel costs, e.g. time for testing and training associated with testing
    - Cost of connecting data to information system(s)
    - Reimbursement

Test System Considerations

- Considerations specific to a particular test system
    - Accuracy and precision published in product insert
    - Simplicity of test system/instrument operation, maintenance, and reliability
    - Determine the level of technical support provided by the manufacturer
    - Sales restrictions such as
        - Training requirements for testing personnel
        - Quality assurance program
        - Provision of test information to patients
    - Include customer letter in every waived test system stating the responsibility for each testing site to obtain a CW and use the test properly
    - Test interpretation and reporting
        - Test performance limitations
        - Precautions for color-blindness
        - Confirmatory or referral testing
            - Status of the disease process can affect test results
    - Public health disease reporting requirements
        - Provide examples of reportable diseases

Appropriate Personnel

- Appropriate personnel considerations for testing
    - Sufficient staffing in place, effect of turnover
        - Temporary or part-time personnel may be less proficient in performing the test appropriately
        - Determine whether current staff have adequate time to perform testing
    - Overall staff competency, training required
        - Need to ensure the test can be performed consistently and the correct result obtained
        - Staff should have periodic retraining/reminders to maintain good testing procedures
    - Identify a resource person or expert to answer questions
        - May be in the office or available by phone/hotline
        - May be from the reference laboratory, state health department, manufacturer's technical assistance
    - Post telephone numbers for health departments
    - Post 800 telephone numbers for the manufacturer/distributor of each test system
    - Encourage staff to ask/call for help
    - There should be a "contact person" for questions or to discuss new test systems/kits with sales representatives. This person needs the appropriate information or training to know what to ask sales representatives or distributors.

Pre-testing Phase (test ordering and specimen collection)

- Activities or practices to promote quality in the pre-testing phase
    - Test requisition/orders
        - Acknowledge anonymous testing considerations
        - Acknowledge HIPAA applicability to waived testing
        - Confirm patient identification, test ordered- include examples to illustrate how to confirm and document patient identification
    - Provide patient instructions, patient information as necessary
        - Give examples, e.g. fasting for glucose
        - Ask patients if they were given instructions, did they understand them, and can they explain them
        - Discuss factors, test limitations or medical indications that can affect test results with the patient, as appropriate
    - Specimen collection and handling
        - Use only direct unprocessed specimen(s) approved for the test – give examples
        - Serum and plasma are not appropriate specimens for waived testing
        - Follow the specimen collection procedure specified in the product instructions
        - Use container/collection device provided with the test
        - Label the specimen (patient identifier; date; person collecting; time, if needed)
        - Follow manufacturer's instructions for handling, storage and disposal

- Before testing, prepare testing materials (kit, reagents, controls, etc.)
    - Check product inserts for changes in instructions
    - Check expiration dates
        - Write date opened and expiration in marker on the outside container of kit, vial, etc.
        - Explain that expiration dates may change due to other factors (e.g., based on storage, temperature, once opened)
        - Explain the importance of adhering to manufacturers' expiration dates (give examples)
    - Control ranges may change with lot numbers – refer to current lot number information
    - Do not mix components of different manufacturers' kits, lots or tests

Testing Phase (performing the test and interpreting results)
Activities or practices to promote quality in the testing phase

- Written test procedures
    - Have a current procedure manual
        - May include manufacturer's product inserts and various forms for reporting diseases to public health departments
        - Include established reference ranges, critical and action values, as applicable, for each test system
    - Each testing procedure should be written with instructions that include all steps for your facility
        - Use a format or template to write new procedures
        - Written procedures should integrate procedural steps and control testing instructions
    - Follow current manufacturer's instructions for test system in use
        - Check product inserts for any changes in instructions
        - It may be useful to highlight the most important parts of procedures
    - Read, understand instructions prior to testing
    - Separate retired procedures, retain and document inclusive dates of service
    - Laboratory director or responsible person should review periodically
    - Use Quick Reference Instructions that include the specific test name at workstation
- Procedural steps
    - Set up testing materials, instrument, workstation
        - Electronic equipment
            - Include a warning that if "portable" equipment is moved, it may be subject to inaccurate results and may require additional quality assurance to verify it is fully functional and operating properly
    - Follow the steps in the order described, including control procedures and control testing
    - Follow manufacturer's timing for test performance and interpretation
        - Include hints for timing tests
        - Explain the importance of correct timing for tests and how inaccurate timing can affect results – provide examples

    - Emphasize “do not mix components of different manufacturers’ kits, lots or tests”
    - Check and document test system lot number and expiration date
        - Explain the importance of documentation (e.g., tracking or traceability of product recalls)
    - Include precautions for batch testing and for performing a variety of different tests simultaneously (e.g., labeling, identification, timing)
    - Stress the importance of not altering test components, e.g., cutting test cards, strips
- Control testing
    - Explain what quality control is, why it is important, how to perform and interpret results
    - Perform at intervals stated by manufacturer
    - Understand types of test system controls – define in a glossary
        - Built-in/internal
        - Procedural
        - Electronic
        - External control materials
    - Inform manufacturer or distributors to either supply external control materials with test kits, when possible, and include instructions for use, or provide information for user to purchase appropriate control materials
    - Document results of internal and external control testing and actions taken if out-of range
    - For external controls, document lot numbers and expiration dates
- Test results – interpretation and recording
    - Follow manufacturer’s instructions for result interpretation and recording
    - Evaluate the results–determine whether the test result is reasonable for the patient – include examples
    - Records of patient test results may include
        - Test name, lot number, expiration date
        - Patient or specimen identifier
        - Test results, date performed, initials of person performing
        - Control test results may be recorded with patient test results
    - Test system problems/failures
        - Refer to manufacturer’s instructions for
            - Identifying sources of error, interferences - drugs, nutritional additives can affect a test
            - Steps to resolve problems
            - Problems with control testing
            - Manufacturer contact information for assistance
            - FDA MedWatch medical products reporting program and contact information (Note: this is not in current product instructions)
    - Resolve problems before reporting patient results
    - Record actions taken to resolve problems including actions taken when control results are unacceptable
    - Maintain records for the minimum timeframe required by state regulations, if applicable

- Provide staff with contact information for "Go To" person such as a consultant/resource person
- Encourage staff to request help with problems

Post-testing Phase (reporting results and maintaining records)

Activities or practices to promote quality in the post-testing phase

- Test results should be easily retrievable
- Reporting results
  - Use the correct reference ranges
  - Results should not be reported if there is a question about the procedure or how the test was performed
  - Test results should not be released until problems are resolved
  - Assure written reports are legible, reported in a timely manner to the appropriate person
  - Point-of-care/office testing results may be accurately and legibly recorded directly in patient's medical record (for practices with multiple locations, note the office where testing was performed.)
  - Have a process for reporting critical or action values, and ensure that testing personnel are aware of critical or action values for each testing site
  - Issue verbal reports and critical values according to testing site policies; follow with a written report
    - Confirm and document verbal communications. Emphasize and explain read-back of critical results to confirm verbal report
- Reports may include information appropriate for the facility
  - Testing facility information
    - Name, address/site/clinic number, phone number (suitable to the type of facility)
    - Director/person responsible for the facility
  - Patient information/identifier
  - Date report is issued, person issuing report when appropriate
  - Relevant test information
    - Results with appropriate units, interpretation, reference ranges (normal values)
    - Date performed
    - Comments, if appropriate
- Standardized report format should be appropriate for the testing site so reports generated onsite are easily distinguishable from referral laboratory reports. Example: A notation in the policy or procedure manual could indicate "Unless otherwise specified, all testing is performed in this facility."
- Comply with local, state disease reporting requirements
  - Provide contact information
- Confirmatory/supplemental testing
  - Emphasize the importance of following initial waived test results with confirmatory/supplemental testing, when needed, since many waived tests are screening tests. Stress whenever confirmatory testing is necessary, it should be stated in the product insert
  - Give examples

    - Follow testing protocol required by your facility or manufacturer's instructions
        - Provide specific information about the sample type and identification and test(s) ordered when referring samples for confirmatory/supplemental testing
    - Consult the ordering physician
    - Collect a new specimen if necessary
    - Follow safe specimen transport procedures
        - Specific instructions may be provided by the referral laboratory receiving the patient sample
        - Have contact information readily available
        - Post instructions for easy reference
    - Use only CLIA-certified laboratories for referral
        - Clarify that laboratories performing confirmatory/supplemental testing must be CLIA-certified. Note: If results of testing performed in a research facility are used to treat patients, the facility must be CLIA-certified
    - Record information for tracking
        - Provide adequate information to identify the sample source for testing
        - Link referred specimen to patient identifier
        - Test request, date referred, referral laboratory
        - Referred test results, date received and date reported
    - Maintain copies of referred test reports
    - Issue and maintain reports of supplemental testing
- Retain all patient test results
- Retain records of controls, calibration records, instrument maintenance, repairs and replacements

Personnel Training & Continuing Education

- General
    - Emphasize the need for patient confidentiality and give examples of circumstances where breaches of confidentiality could occur
    - Include a thorough explanation of Universal Precautions—for example, the need for changing gloves between patients may not be obvious to non-laboratorians
    - Emphasize safety and QC procedures as two major components requiring training
    - Stress the HIPAA law applies to waived testing and include the HIPAA website (http://www.hhs.gov/ocr/hipaa).

- Mechanisms for providing training and continuing education to waived testing personnel
    - Personnel training – personnel turn-over is a major challenge and adequate staff and proper training of personnel are essential for quality testing
        - Personnel must be trained/oriented to each test procedure before testing patient samples
        - Ensure competency before patient testing

        - Include training in specimen collection
        - Include training in bloodborne pathogens
    - Define and describe on-the-job training
        - Give examples
        - The trainer demonstrates the procedure/steps involved
        - The trainee performs the test to demonstrate understanding and ability to perform the test correctly
        - Training should be provided by a qualified person who can train, provide feedback, evaluate staff and conduct follow-up evaluations to ensure training is effective and competency is maintained
    - Training modules or activities should be specific for different intended audiences
    - Training and competency assessment must be on-going
    - Manufacturers and distributors provide technical assistance, product updates, notifications and may provide training
- Competency assessment
    - Define "competency" in a glossary, as it is a difficult concept to convey
    - Periodically assess testing personnel
    - External evaluation programs and control materials can be used for competency assessment
    - Participate in voluntary proficiency testing (PT)
        - Explain what PT is and how to obtain it
        - Explain participation in voluntary PT programs ensures testing is accurately performed
- Training/continuing education sources
    - Manufacturers, distributors
    - Professional organizations – American Society for Clinical Laboratory Science, College of American Pathologists, COLA, Joint Commission on Accreditation of Healthcare Organizations, etc.
    - State laboratories, reference laboratories
    - Centers for Disease Control and Prevention
    - CMS
    - FDA
    - National Laboratory Training Network
- Other considerations/sources for training or continuing education
    - Provide on-line internal audits based on checklists for laboratories to assess their performance.
      (Note: Many physician office laboratories [POLs] do not have internet access)
    - Provide consultation to POLs, when requested. This could be a service financed with user fees
    - Provide education to physicians at group meetings, national meetings, COLA, other organizations with free training
    - Suggest using a coordinated approach that includes working through public health systems

Disseminating Good Laboratory Practice Guidelines

- Consider *MMWR Recommendations and Reports* as the comprehensive source document
    - Mail a copy of the *MMWR Recommendations and Reports* publication to professional organizations and encourage dissemination to their members
    - Request State Survey Agencies to mail a copy of the guidelines to Certificate of Waiver applicants
    - *MMWR* may offer CMEs for physicians to receive educational credit related to laboratory testing/use
- Provide information for risk managers, physicians, managed care providers, insurance companies, malpractice carriers, hospital administrators, American College for Physician Executives, Medical Group Management Association, HIV/AIDS educators, professional organizations, etc., to inform them that following good laboratory practice guidelines may lower the legal risk to their organizations
- Develop and distribute a Top 10 list of most important good laboratory practices for waived testing
    - Suggested Top 10 subjects: specimen, reagents, QC, reports, training/competency, records, procedure, patient ID, expert in office, expert to call
    - To develop the Top 10 for different user groups, use focus groups (the intended audience) for input – especially on mode of dissemination
    - Design and distribute wall posters, laminated handouts featuring the Top 10 list
- Manufacturers and distributors could endorse good laboratory practices for waived testing guidelines in product information
- Collaborate (Health Industry Distributors Association [HIDA] with CDC) to devise an educational tool to be provided at no charge to customers and posted on the HIDA website.
- Important part of effort is to reach patients/consumers; determine mechanisms to reach the public
    - Provide posters with information for patients explaining what they should expect from laboratory testing
- Guideline information needs to be provided in languages other than English
- Websites
    - Post guidelines on the CMS website
    - Provide a web cast via Public Health Training Network
    - Recommend manufacturers and distributors post links to the guidelines on their websites
    - The HIDA website will have a CLIA Resource Center

Additional Comments

- CDC publication is a powerful tool; “Recommendations” can become a standard of care
    - Ensure the publication is accessible, understandable, and simple enough to be useful
    - Use a uniform format or consistent language
        - Identify which recommendations are the most critical
        - Provide an acronym table to explain CLIA, OSHA, HIPAA, etc.
        - Use different approaches for different user populations

        - Vary reading level according to targeted audience
    - Provide information for physicians on the simplest ways to comply with the guidelines
- Physicians and healthcare professionals want to do their best but do not have adequate training in laboratory testing
- Stress that patient safety is the goal, and not performing some type of quality assurance increases liability
- Variability among product inserts makes it hard to find needed information
- In the guidelines, include a glossary of terms with definitions or provide an explanation in simple terms
    - Accuracy
    - Competency
    - Confirmatory test
    - Laboratory – any site where testing is performed
        - Use appropriate language to relate to physician office personnel, nurses, physicians, office managers because they do not think of their testing as laboratory testing, nor their facility as a laboratory
    - "Laboratory director/manager" is an unfamiliar term for those who do not see their activities as directing/managing a laboratory; "responsible party" may be a better term
    - Precision
    - Proficiency testing – present as an educational tool
    - Quality control, including types of controls
    - Screening test
    - Test system
- Emphasize the importance of documentation, e.g., control results, verbal reports, throughout the publication
- If feasible, include a list of analytes with waived test systems available. Include link to FDA waived test web site
- Provide section or table for HIV testing and other infectious disease special considerations
- Explain the difference between manufacturers and distributors
- Provide a generic template of a product insert to identify key points/information
    - Explain the intent of language used in inserts such as, "should," "may," vs. "must"
- Caution laboratories to abide by manufacturer's intended use of test systems
- Provide checklists or table of key waived testing concepts and/or steps for the laboratory director ("responsible party") and testing personnel
- Reference the JCAHO National Patient Safety Goals
- Use CLSI documents as a reference